

U.S.S.N. 09/760,046

Filed: January 21, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks**Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 1, 3, 4, 6-13, 15-23, 25, 26, 34, and 35 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

In response to the Examiner's rejection, claims 1 and 3 have been amended to correct antecedent basis. Claim 1 has been amended to delete "dry" from the preamble. The last step recited in claim 1 forms a dispersion of solid microparticles of agent in a solvent. Claim 3 has been amended to state that the dispersion of solid microparticles of agent is encapsulated in an encapsulating material. Support for this amendment can be found in the specification at least at page 8, lines 20-22. Therefore the claims as amended are definite.

Rejection Under 35 U.S.C. § 103

Claims 1, 3, 4, 6-13, 15-23, 25, 26, 34, and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 98/46212 to Shah ("Shah"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Legal Standard

The steps listed in a method claims are not ordinarily construed to require an order, *unless* (1) the method actually recites an order or (2) the method steps implicitly require that they be performed in the order written. *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1369, 65 U.S.P.Q.2d 1865 (Fed. Cir. 2003), affirming the legal standard stated in *Interactive Gift Express*,

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Inc. v. CompuServ Inc., 256 F.3d 1323, 59 U.S.P.Q.2d 1401 (Fed. Cir. 2000). The two-part test for determining if the method steps implicitly require a specific order is: (1) look to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written, and (2) if the first test has not been met, look to the rest of the specification to determine if it directly or implicitly requires a specific order. *Id.* at 1370.

The claimed methods

Claim 1 defines a method for forming micronized particles of an agent. Claim 1, as amended, requires:

- (a) dissolving a macromolecular material in an effective amount of a solvent, to form a first solution;
- (b) dissolving the agent in an effective amount of a solvent, to form a second solution;
- (c) adding the second solution to the first solution to form an emulsion and thereby micronize the particles of the agent;
- (d) freezing the emulsion;
- (e) drying by vacuum the frozen emulsion to form solid micronized particles of the agent dispersed in solid macromolecular material; and
- (f) then, dissolving the macromolecular material having dispersed therein solid micronized particles of agent in an effective amount of a solvent for the macromolecular material to form a dispersion of solid microparticles of agent in the solvent, wherein the solvent is a non-solvent for the agent. (emphasis added)

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Applying the first part of the test recited above demonstrates that claim 1 requires steps (a) and (b) to be performed before step (c) and the remaining steps to be performed in the order they are written. In steps (a) and (b), two solutions are formed. In step (c), the second solution is added to the first solution to form an emulsion. Thus the step (c) cannot occur until after steps (a) and (b) have been completed. Steps (d), (e), and (f) each refer to an element formed in the previous step. Step (e) was amended to specify that the emulsion is frozen. Support for the amendment to step (e) can be found in the specification at least at page 7, lines 28-29. Step (f) was amended to specify that it follows step (e). Support for the amendment to step (f) can be found in the specification at least at page 8, lines 6-7 and 11-12. Therefore the grammar used in claim 1, as amended, makes explicit the order in which the steps are performed.

Shah

Shah describes a process for encapsulating proteins to form sustained release compositions. Shah's method requires forming a double emulsion (steps 1 through 3, listed below) and freezing the double emulsion (step 5, listed below) (see also Figure 1). Shah requires the following steps:

- (1) dissolving a polymer in an organic solvent to form a polymeric solution,
- (2) adding an active agent to the polymeric solution to form a first emulsion or suspension,
- (3) dispersing the first emulsion or suspension in a continuous phase to form a dispersion,
- (4) adding an excipient to the dispersion,

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(5) freezing the dispersion, and
(6) lyophilizing the frozen dispersion to remove solvents and produce microparticles containing protein. (see Shah, page 6, lines 7-16)

In step (3), Shah disperses the first emulsion or suspension in a continuous phase to form a dispersion (also known as a double emulsion); in step (5), Shah freezes the dispersion or double emulsion. In contrast, claim 1 requires forming a single emulsion and freezing the single emulsion. Although claim 1 uses "comprising" language, which allows additional steps to be added, the steps that are recited in the claim must be disclosed or suggested by a prior publication, for the publication to make the claim obvious. Shah's additional step of dispersing the first emulsion in a continuous phase to form a dispersion changes the composition that is subsequently frozen. Therefore Shah does not disclose steps (d), (e), and (f); and Shah must be describing a method that requires different steps than those listed in claim 1, as amended.

Shah explains that its method is a new and improved process for encapsulating proteins. Shah emphasizes that direct lyophilization of the double emulsion "refines and simplifies [Shah's] process over previously described processes." (Shah, page 15, lines 5-7) Thus, Shah emphasizes the importance of freezing and drying the double emulsion. Shah does not suggest modifying its process to lyophilize a single emulsion.

Finally, Shah describes a method for the encapsulation of proteins, not a method for reducing the particle size of proteins. Therefore, there is no suggestion to modify Shah so that it forms a single emulsion and freezes the single emulsion, as required by claim 1. Additionally,

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there is no suggestion to follow the lyphoilization step with a step that dissolves the encapsulating polymer a solvent to form a dispersion of solid microparticles of agent in the solvent. Such a step defeats the purpose of the entire method, because it would remove the encapsulating material. Therefore, claims 1, 3, 4, 6-13, 15-23, 25, 26, 34, and 35 are non-obvious in view of Shah.

Additional amendments to the claims

Claim 1 has been amended to insert a new step b, which specifies that the agent is dissolved in an effective amount of a solvent to form a second solution. Support for this amendment can be found in the specification at least at page 7, line 9. Claim 1 has been further amended to correct the grammar in the claim in view of the added step. Claim 4 has been amended to correct a grammatical error.

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NO. 3219 R. 12

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Allowance of claims 1, 3, 4, 6-13, 15-23, 25, 26, 34, and 35, as amended, is respectfully solicited.

Respectfully submitted,

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Date: February 18, 2005

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